K102315

SPINE WAVE

510(k) Summary
StaXx® XDL System

AUG 19 2011

1. Submitter Information

Submitter:	Spine Wave, Inc.
Address:	Three Enterprise Drive Suite 210 Shelton, CT 06484
Telephone:	203-712-1847
Telefax:	203-944-9493
Contact:	Denise Duchene
Date Prepared:	January 17, 2011

2. Device Information

Trade Name:	StaXx® XDL System
Common Name:	Vertebral Body Replacement
Classification Name:	Spinal Intervertebral Body Fixation Orthosis
Classification/Code:	Class II per 21 CFR 888.3060; MQP

3. Purpose of Submission

The purpose of this submission is to introduce to market a new vertebral body replacement device, the StaXx® XDL System.

4. Predicate Device Information

The StaXx® XDL System described in this submission is substantially equivalent to the following devices:

Predicate Device	Manufacturer	510(k) No.
StaXx® XD System	Spine Wave, Inc.	K052670 K090315 K101288
Nuvasive CoRoent® System	NuVasive, Inc.	K052210
Exactech Octane Device	Exactech, Inc.	K070218
Concorde Bullet Device	DePuy Spine, Inc.	K052746

5. Device Description

The StaXx® XDL System is composed of wafers that are stacked into an expandable implant to adjust the height of the implant. The implant components are manufactured from PEEK-OPTIMA with 6% Barium Sulfate and contain tantalum markers for additional visualization under fluoroscopy. The system also includes a delivery device to place and expand the system.

6. **Intended Use**
The StaXx® XDL System is a vertebral body replacement device intended for use in the thoracolumbar spine (T1-L5) to replace and restore height of a collapsed, damaged, or unstable vertebral body or portion thereof, due to tumor or trauma (i.e., fracture). The system is to be used with autograft or allograft and supplemental spinal fixation.

7. **Comparison of Technological Characteristics**
The substantial equivalence of the subject StaXx® XDL System is shown by similarity in intended use, indications for use, materials and performance to the cited predicate devices. The StaXx® XDL System and the predicate devices are manufactured from PEEK-OPTIMA with 6% Barium Sulfate and contain wafers that are stacked into an expandable implant. These devices are all used as vertebral body replacement devices in the thoracolumbar spine.

8. **Performance Data**
Non-clinical testing was performed to demonstrate that the subject StaXx® XDL System is substantially equivalent to the listed predicate devices. The testing, performed to ASTM F2077 and ASTM F2267, included:
   - Static axial compression,
   - Dynamic axial compression,
   - Static torsion,
   - Dynamic torsion,
   - Static subsidence,
   - Static expulsion,
   - Static shear testing, and
   - Wear debris.

9. **Conclusion**
Based on the indications for use, technological characteristics, performance testing and comparison to predicates, the subject StaXx® XDL System has been shown to be substantially equivalent to the predicate devices identified in this submission, and does not present any new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Spine Wave, Inc.
% Ms. Denise Duchene
Three Enterprise Drive, Suite 210
Shelton, Connecticut 06484

AUG 19 2011

Re: K102315
Trade/Device Name: StaXx® XDL System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: August 12, 2011
Received: August 15, 2011

Dear Ms. Duchene:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

A. Indications for Use

510(k) Number (if known): K102315

Device Name: StaXx® XDL System

Indications for Use:

The StaXx® XDL System is a vertebral body replacement device intended for use in the thoracolumbar spine (T1-L5) to replace and restore height of a collapsed, damaged, or unstable vertebral body or portion thereof, due to tumor or trauma (i.e., fracture). The system is to be used with autograft or allograft and supplemental spinal fixation.

Prescription Use __X___ (Part 21 CFR 801 Subpart D) And / Or Over-The-Counter-Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K102315